PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Ruy Tchao	Examiner:	L. Wong
Serial No.:	09/472,490	Group Art Unit:	1761
Filed:	December 23, 1999	Docket:	102-302 RE/CON
For:	CHEMOTAXIS ASSAY PROCEDURE	Dated:	April 18, 2002

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APPEAL BRIEF PURSUANT TO 37 C.F.R. §1.192

Sir:

This is an appeal to the Board of Patent Appeals and Interferences from a decision mailed March 30, 2001 wherein the Examiner finally rejected claims 46-48 and 50. Other claims 1-15 have been allowed, and claim 49 has been objected to. Appellants have timely filed a Notice of Appeal with extension of time by certification on September 28, 2001. This Brief is being filed in support of that Notice of Appeal. As required by 37 C.F.R. §1.192, this Brief is being filed in triplicate. The fee of $320.00 for filing this Brief is provided by check, enclosed herewith. Please charge any additional fees or credit any overpayments to Deposit Account No. 08-2461.

The PTO did not receive the following listed item(s) A check of $320.00

I. REAL PARTY IN INTEREST

The real party of interest in the present appeal is Ruy Tchao, the sole inventor and owner of the entire right, title and interest in and to the above-identified application. For completeness, it is noted that the inventor and owner has exclusively licensed his rights in and to the application.

II. RELATED APPEALS AND INTERFERENCES

No related appeals or interferences are presently pending which are known to Appellant, Appellant's legal representative, or licensee which will directly affect, be directly affected by, or have a bearing on the Board's decision on this Appeal.

III. STATUS OF THE CLAIMS

Claims 1-15 are pending and stand allowed in this application.

Claim 49 is pending in this application and is objected to as being dependent upon a rejected base claim (claim 48).

Claims 46-48 and 50 are pending in this application and are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not disclosed in the

specification in such as way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 46-48 and 50 are also rejected under 35 U.S.C. §251 as being improperly broadened in a reissue application.

IV. STATUS OF AMENDMENTS

The Examiner finally rejected claims 46-48 and 50 of the above-identified application in an Office Action mailed on March 30, 2001. Applicant filed a Response Pursuant to 37 C.F.R. §1.116 on June 18, 2001, traversing the rejections of claims 46-48 and 50. In an Advisory Action mailed on July 9, 2001, the Examiner considered the request by Applicant for reconsideration in the Response filed on June 18, 2001 but stated that the Response did not place the application in condition for allowance, thereby maintaining the rejections of claims 46-48 and 50 for the reasons set forth in the final Office Action. Other than the Notice of Appeal, no further response by Applicant has been presented to the Advisory Action.

V. SUMMARY OF THE INVENTION

The invention defined by the claims on appeal relates to a cell migration assay procedure comprising measuring the migration of cells across a radiation opaque membrane, wherein the procedure is non-destructive of the cells. (Specification at column 5, lines 63-67 to column 6, lines 1-9.)

One particular aspect of the cell migration assay procedure includes the steps of placing cells in a first chamber and labeling such cells therein. The first chamber is separated from a second chamber by the radiation opaque membrane and cell presence is measured in the second chamber by detecting labeled cells in the second chamber without substantially detecting labeled cells in a first chamber. (Specification, column 3, lines 56-67 to column 4, lines 1-2, and column 4, lines 46-54.)

Another aspect of the cell migration assay procedure includes the further step of inducing the migration of cells across the radiation opaque membrane, the inducing step being particularly practiced by placing a chemical agent in the second chamber capable of creating a chemotactic reaction with the cells. (Specification at column 3, lines 63-67 through column 4, lines 1-2.)

Another aspect of the cell migration assay procedure is provided wherein the labeling step includes labeling the cells with a dye. (Specification at column 5, lines 12-29.)

VI. ISSUES ON APPEAL

The issues on appeal are as follows:

1. Whether nothing within the scope of claims 46-48 and 50 is enabled by the subject matter contained within the specification of the subject '997 patent, for which reissue is sought.

2. Whether claims 46-48 and 50 are improperly broadened in the reissue application under 35 U.S.C. §251.

VII. GROUPING OF CLAIMS

Claims 46-48 and 50 should be considered as one grouping. For purposes of the present Appeal, it is respectfully submitted that independent claim 46 meets the statutory criteria for patentability. The patentability of dependent claims 47-48 and 50 will be predicated thereon.

VIII. ARGUMENTS

A. REJECTIONS UNDER 35 U.S.C. §112

1. The Rejection of Claims 46-48 and 50 under 35 U.S.C. §112, First Paragraph, is Improper.

The Examiner rejected claims 46-48 and 50 under 35 U.S.C. §112, first paragraph, as

> **containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.**

A lack of enablement rejection under §112, first paragraph, is appropriate where the written description fails to teach those in the art how to make and use the invention as broadly as it is

claimed without undue experimentation. See *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). In accordance with the Manual of Patent Examining Procedures (M.P.E.P.), §706.03(c), such lack of enablement rejection may take several forms. Under a "general enablement" rejection, where it is the Examiner's position that nothing within the scope of the claims is enabled, the Examiner would use form paragraph 7.31.02 for the rejection. Under a "scope of enablement" rejection, where it is the Examiner's position that something within the scope of the claims is enabled, but the claims are not limited to that scope, form paragraph 7.31.03 would be used by the Examiner. In the subject application, the Examiner applied the language of the "general enablement" form, which appears to be inconsistent with the Examiner's actions and statements. The Examiner contends in support of the rejection that only non-destructive chemotaxis assays are contemplated. Consistent with that position, the Examiner has only objected to dependent 49, since that claim relates to a chemotactic reaction. As such, the Examiner acknowledges that the written description at least enables something within the scope of the rejected claims. Withdrawal and/or correction of this rejection is respectfully requested, so that under the appellate review the correct standards and law can be applied. See *In re Cortright*, 165 F.3d 1353 (Fed. Cir. 1999).

2. **The Rejected Claims are Limited to Cell Migration Assay Procedures and are Not Directed to Any Non-Destructive Assay Procedures.**

The Examiner, in support of the rejection of claims 46-48 and 50 under 35 U.S.C. §112, first paragraph, states that Applicant does not teach "any and all types of non-destructive assays", nor does Applicant teach "any and all types of inducing agents". The Examiner states that only non-destructive chemotaxis assays are contemplated and only

chemical agents for inducing the migration of cells are contemplated. However, in independent reissue claim 46, Applicant is not broadly claiming any and all types of non-destructive assay procedures, but is instead claiming a "cell migration assay procedure". It is submitted that the recited steps of the claimed cell migration assay procedure are sufficiently described to enable one skilled in the art to practice the claimed cell migration assay procedure.

Claim 15 of the original patent, which has again been allowed by the Examiner, recites as follows:

> **A chemotaxis assay procedure comprising measuring the migration of cells across a radiation opaque membrane, wherein said procedure is non-destructive of said cells.**

Independent reissue claim 46 of the present application recites as follows:

> **A cell migration assay procedure comprising measuring the migration of cells across a radiation opaque membrane wherein said procedure is non-destructive of said cells.**

Claim 46 differs from allowed claim 15 only in that the preamble of claim 15 recites a **chemotaxis assay procedure** while the preamble of claim 46 recites **a cell migration assay procedure**. As the Examiner is well aware, chemotaxis is merely one technique to effect cell migration. While the specification of the present application specifically refers to the use of chemotaxis to effect cell migration, the concept which is required to practice the present invention is to effectively induce cell migration across a membrane. One common technique for inducing cell migration is to use a chemo-attractant.

The specification of the present application clearly describes the use of a chemo-attractant to effect such cell migration. However, reading the specification as a whole, it is clear that use of a chemo-attractant is merely the preferred method of causing cell migration. It is cell migration itself, not the manner in which the cells are induced to migrate, which forms a significant part of the broad concept of the cell migration assay procedure of the present invention.

There are several specific recitations in the specification of the present invention which indicate that cell migration, in a general sense, is more significant than the specific method of attracting the cells across the membrane. For example, column 4, lines 50-54, recites as follows:

> **Accordingly, the radiation measured will provide a direct quantitative measure of the number of cells that have migrated across the radiation opaque membrane 10 from chamber 24 to chamber 22.**

Clearly, the operative measurement is cell migration rather than any particular attractant used to effect cell migration. Further, at column 6, lines 27-32, it is clearly noted that the inventive membrane of the present invention permits the migration of cells across the membrane. Use of a membrane, particularly a radiation detecting membrane, as required in claim 46, is independent of the particular attractant which causes the cells to migrate therethrough.

Finally, the Examiner's attention is again called to the specification of the present application at column 5, lines 30-46. The Examiner will note that this portion of the

specification describes the membrane which allows cells to migrate therethrough. This portion of the specification describes, in detail, the ability to have labeled cells migrate across the membrane and be measured by electromagnetic radiation which has been used to stimulate the labeled cells. A significant advantage of the assay procedure of the present invention is that it is non-destructive of the cell sample, and thus permits repeated measurements of the same test sample at different time intervals. Nowhere throughout this description of the salient features of the invention is there any reference to chemotaxis or to a chemo-attractant. Clearly, at the point where the invention considered his invention novel, the inventor found no need to describe the particular attractant used to effect migration of the cells.

With the specification clearly describing a membrane, particularly a radiation detecting membrane and its properties for use in measuring migration of cells thereacross, it is submitted that the broad concept of a **cell migration assay procedure**, to which all rejected claims are directed, is sufficiently enabled.

3. The Claimed Invention Can Be Practiced Without Undue Experimentation.

As noted hereinabove, not just any non-destructive assay procedure as contended by the Examiner, but the claimed **cell migration assay procedure** can be practiced as set forth in the specification by measuring cell migration across a membrane as described. In column 5, lines 63-66, the specification states that:

> **In accordance with the present invention, such membranes permit the measurement of radiation emitting from the**

labeled cells that have migrated through the radiation opaque membrane... (emphasis added).

That the specification states that there is a significant advantage of the **present invention** over prior "procedures" clearly indicates that the phrase "present invention" relates to the cell migration assay procedure, and not just the membrane. (See column 6, lines 2-3.) The specification at column 6, lines 4-9, goes on to further explain how the cell migration assay procedure of the present invention avoids certain tedious procedural steps of the prior art. Of significance in this description of the **present invention** is the lack of any statement that would restrict the invention to only a chemotaxis assay procedure. In fact, the specification clearly states that the radiation opaque membrane may be of any convenient construction, "so long as it has the properties mentioned above" (column 6, lines 10-13). Such properties are clearly defined in column 5, lines 30-61, and elsewhere in the specification. Accordingly, any skilled artisan who wishes to practice the claimed cell migration assay procedure would be enabled, without any undue experimentation to perform the measurement step as recited, so long as the membrane has the properties described. That some experimentation may be required to determine the desired or convenient construction of the radiation opaque membrane is not fatal to the enablement of the claimed invention, so long as the experimentation is not undue. *In re Vaeck*, id. It is submitted that if the membrane is constructed to have the properties clearly outlined in the specification, no undue experimentation would be necessary to practice the claimed steps in any cell migration assay procedure.

4. **Limiting Claims to only Chemotaxis Assay Procedures is Not Warranted and would be Unduly Restrictive.**

As set forth hereinabove, there is commensurate support in the specification to enable one skilled in the art to practice the claimed invention of a cell migration assay procedure without undue experimentation. While it is acknowledged that a preferred form of the cell migration assay procedure is the chemotaxis assay procedure, the broad concept of the invention is the cell migration assay procedure. There is nothing in the specification that limits the use of a cell migration assay procedure to only chemotaxis assay procedures. Further, there is nothing in the prosecution history that limits the invention to only chemotaxis assay procedures. At the time of filing of the subject application, the inventor chose to then claim the chemotaxis assay procedure. Upon filing the reissue application within two (2) years of issuance of the '997 patent, it became apparent that the inventor was entitled to more than originally claimed. With sufficient enabling description in the specification, and in the absence of file history estoppel, the inventor is entitled to claims of scope that are at least commensurate with the description, even though every conceivable embodiment may not be described. In a recent related context where claims were not interpreted to incorporate the preferred embodiment, the Federal Court in *Rexnord Corp. v. Latham Corp.* stated:

> **Our case law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.... "[I]f structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims. Nor could an applicant, regardless of the prior art, claim more broadly than that embodiment."...In short, it is the claims that measure the invention, as informed by the specification. As we noted long ago: "Specifications teach. Claims claim."**
> (Fed. Cir., No. 00-1395, November 15, 2001)

Since there is adequate support in the specification to satisfy the enablement requirement of the broader claims directed to a cell migration assay procedure, it would be legally improper to limit the invention to the preferred embodiment of that procedure.

The rejected claims 46-68 and 50 being enabled as required under 35 U.S.C. §112, first paragraph, it is respectfully requested that the rejections thereof be withdrawn.

B. THE REJECTION UNDER 35 U.S.C. §251

The Examiner has rejected claims 46-48 and 50 as being improperly broadened in a reissue application, contending that the Applicant does not teach any and all types of non-destructive assays or any and all types of inducing agents. When a reissue applicant seeks to obtain a broadened version of a claim in the patent, one may look to see whether the disclosure reasonably conveys to one skilled in the art that the inventor had possession of the broad invention at the time the original application was filed. See *In re Weiler*, 790 F.2d 1576 (Fed. Cir. 1986). Unlike any and all types of non-destructive assays which the Examiner contends are not enabled by the specification of the subject application, it has been shown herein that the broadened version of the invention claimed in the subject application is directed to a cell migration assay procedure. Applicant has demonstrated that he indeed was in possession of that broad invention at the time the original application was filed because he set forth in the application a written description that would enable a skilled artisan to practice such claimed invention without undue experimentation. As stated by the Federal Circuit in *In re Peters*, 723 F.2d 891 (Fed. Cir. 1984):

> **where, as here, the overall disclosure reasonably conveys to one skilled in the art that the inventor had possession of the broad invention at the time the original application was filed, a claim drawn to that invention is available under compliance with all provisions of §251.** (723 F.2d at 894, emphasis added.)

In the present application the claim drawn to "that invention" is independent claim 46, directed to a cell migration assay procedure. Having satisfied the requirements of §251, it is submitted that the Examiner's rejection thereunder should be withdrawn.

C. OTHER ISSUES

1. New/Supplemental Oath

The Examiner has indicated that because additional errors in the original patent have been corrected through amendments to the claims, a new/supplemental Oath or Declaration in compliance with 37 C.F.R. §§1.63 and 1.75 is required. Upon resolution of the claims presently on appeal, a suitable new/supplemental Oath or Declaration will be provided.

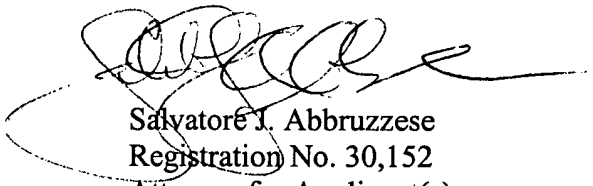
2. Offer to Surrender Original Patent

Upon resolution of the claims on appeal, the original patent and/or an affidavit or declaration as to any loss or inaccessability will be supplied.

IX. CONCLUSION

For the factual and legal reasons set forth hereinabove, it is respectfully submitted that the application, including claims 1-15 and 46-50, is in condition for allowance. Reversal of the Examiner's final rejection of claims 46-48 and 50 is believed to be warranted.

Respectfully submitted,



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CLAIMS CURRENTLY ON APPEAL

46. A cell migration assay procedure comprising measuring the migration of cells across a radiation opaque membrane wherein said procedure is non-destructive of said cells.

47. An assay procedure of claim 46 including the further steps of:

placing said cells in a first chamber;

labeling said cells in said first chamber;

separating said first chamber from said second chamber with said radiation opaque membrane; and

wherein said measuring step includes measuring cell presence in said second chamber by detecting said labeled cells in second chamber without substantially detecting said labeled cells in said first chamber.

48. An assay procedure of claim 47 further including the step of inducing said migration of cells across said radiation opaque membrane.

49. An assay procedure of claim 48 wherein said inducing step includes placing a chemical agent in said second chamber capable of creating a chemotactic reaction with said cells.

50. An assay procedure of claim 47 wherein said labeling step includes labeling said cells with a die.